

12113658

JUN 1-2 2012

Traditional 510(k) Submission
Amplatzer® Vascular Plug 4

510(k) Summary per 21 CFR §807.92

Submitter's Name and Address	AGA Medical Corporation 5050 Nathan Lane North Plymouth, MN 55442	
Establishment Registration No:	2135147	
Contact Name and Information	Sherry Kollmann Senior Regulatory Affairs Specialist Phone: 651-756-5463 Fax: 763-647-5932 e-mail: skollmann@sjm.com	
Trade Name	AMPLATZER® Vascular Plug 4	
Common Name	Vascular Embolization Device	
Classification Name:	Device Embolization, Vascular	
Classification	Class II, 21 CFR 870.3300	
Product Code	KRD	
Predicate Devices	AMPLATZER® Vascular Plug II 510(k) K071125, Reg. No. 870.3300; Product Code: KRD	Predicate Device Intended Use (K071125 and K071699): The AMPLATZER® Vascular Plug is indicated for arterial and venous embolizations in the peripheral vasculature
Device Description	AMPLATZER® Vascular Plug II Extended Sizes 510(k) K071699, Reg. No. 870.3300; Product Code: KRD The AMPLATZER Vascular Plug 4 (AVP4) is a self expanding, Nitinol mesh occlusion device. The device has a radiopaque marker band at each end and a micro screw attachment at one end for attaching to the delivery wire. The device is an extension of the previously approved AMPLATZER Vascular Plugs and has the identical indications for use: arterial and venous embolizations in the peripheral vasculature.	
Intended Use of Device	Included in the AVP4 device package are: <ul style="list-style-type: none"> • Loader - consisting of two tubes, one inside the other with a stainless steel spring attached to extend the inner retractable tube • Delivery Wire - comprised of a PTFE covered coil with core wire and attached end screw The AMPLATZER® Vascular Plug 4 is indicated for arterial and venous embolizations in the peripheral vasculature.	

The AMPLATZER® Vascular Plug 4 incorporates substantially equivalent device materials, packaging materials, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the AGA predicate devices, AMPLATZER® Vascular Plug II (K071125, approved September 9, 2003) and AMPLATZER® Vascular Plug II Extended Sizes (K071699, approved August 15, 2007).

Comparison of Technological Characteristics

In comparison to the predicate device, the AVP4 incorporates the following modifications:

- A change to the shape of the device
- Adaptation of the loader and delivery wire allowing the AVP4 to be delivered through 4 Fr and 5 Fr 0.038" guidewire-compatible diagnostic catheters versus standard off-the-shelf guide catheters
- A change to the finish of the device Nitinol base wire, from black oxide (BO) to chemically etched (CE) finish

The modifications noted above have not altered the intended use or the fundamental scientific technology of the predicate device.

Performance Data

The AMPLATZER® Vascular Plug 4 was subjected to bench testing, biocompatibility testing, and materials testing to support a determination of substantial equivalence to the predicate devices cited. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.

To demonstrate substantial equivalence of the AMPLATZER Vascular Plug 4 to the predicate devices, both *in-vitro* and *in-vivo* testing was performed and outlined below:

The following *in-vitro* performance testing and/or assessment was completed on the AMPLATZER® Vascular Plug 4:

Sterilization	Fatigue
Material Characterization	Product Performance Qualification
Simulated Device Use (Design Verification)	Packaging Performance
Corrosion Resistance	Biocompatibility (Implant and delivery system, ISO 10993-1)
Chemical Characterization (ISO 10993-18)	Toxicology Risk Assessment (ISO 10993-17)
MRI	

The following *in-vivo* performance tests were completed on the AMPLATZER® Vascular Plug 4:

Occlusion Canine Study
Serum Analysis (Porcine Study)
Acute Canine Study

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Conclusion

Based on the intended use, technological characteristics, and safety and performance testing, the AMPLATZER® Vascular Plug 4 has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the AGA currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

JUN 12 2012

AGA Medical Corporation
c/o Sherry Kollmann, RAC
Senior Regulatory Affairs Specialist
5050 Nathan Lane North
Plymouth, MN 55442

Re: K113658

Trade/Device Name: Amplatzer Vascular Plug 4
Regulation Number: 21 CFR 870.3300
Regulation Name: Device Embolization, Vascular
Regulatory Class: Class II
Product Code: KRD
Dated: May 16, 2012
Received: May 17, 2012

Dear Ms. Kollmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFICES/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 113658

Device Name: AMPLATZER® Vascular Plug 4

Indications for Use: The AMPLATZER® Vascular Plug 4 is indicated for arterial and venous embolizations in the peripheral vasculature.

Prescription Use X _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Hilleman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number 10113658

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